

**Section 5- 510(k) Summary**

K 111943

Submitter : St Jude Medical, CRMD  
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Sylmar, CA 91324  
Establishment Registration Number: 2017865

SEP 29 2011

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Date Prepared : September 27, 2011

Trade Name : St Jude Medical Agilis™ PF Introducer System and accessories

Classification : Class II – 21 CFR 870.1340  
Catheter Introducer

Product Code : DYB

Predicate Device: The subject device is equivalent to the following St Jude Medical Device

St Jude Medical Agilis NxT Steerable Introducer - G402049 and 17 Gauge Tuohy Needle

St. Jude Medical Fast Cath Introducer  
(Predicate Device – 13F Obturator)

Device Description : The St. Jude Medical Agilis™ PF Introducer System consisting of a introducer, guidewire, 17Ga Tuohy needle, dilator and obturator is intended to be used to facilitate delivery of SJM devices into the pericardial space for diagnostic and therapeutic purposes

Intended Use: The Agilis™ PF Introducer System is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate electrophysiology studies.

Comparison to Predicate Devices The St Jude Medical Agilis™ PF Introducer system has a similar intended use and the same fundamental scientific technology as the predicate device. All technological characteristics of the Agilis™ PF Introducer system are substantially equivalent to the predicate device including packaging, biocompatibility, sterilization, and labeling. Where

differences exist between the proposed device and the predicate device performance testing demonstrated that these differences do not adversely affect the safety and effectiveness of the proposed device.

Conclusion :

St Jude Medical considers the Agilis™ PF Introducer system to be equivalent to the predicate device listed above. This conclusion is based upon the device similarities in design, technological characteristics, principles of operation, materials and indications for use.

## Introduction

English

The following instructions for Use describe the contents of the St. Jude Medical Agilis™ PF Introducer System and their application in accessing the pericardial space. Please read these instructions thoroughly before using the Agilis PF Introducer System or any of its components to help reduce the potential risks and complications associated with subxiphoid procedures.

Model	Description
DS2D001-25	Agilis PF Introducer System, Small Curl
DS2D001-35	
DS2D003-25	Agilis PF Introducer System, Medium Curl
DS2D003-35	

## Agilis™ PF Introducer System Description

The Agilis™ PF Introducer System consists of the following components:

- Deflectable introducer, 13 French
- Dilator
- Guidewire
- Obturator
- 17Ga Tuohy Needle

The deflectable introducer is fitted with a hemostasis valve to minimize air introduction during introducer insertion and/or exchange. A sideport with a three-way stopcock is provided for air or blood aspiration and fluid infusion. A handle equipped with a deflection control mechanism deflects the tip up to 90° both clockwise and counterclockwise. The introducer features a radiopaque tip marker to improve fluoroscopic visualization.

## Indications

The Agilis™ PF Introducer System is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate cardiac diagnostic and therapeutic procedures, electrophysiology studies.

## Contraindications

- Congenital absence of the pericardium
- Absence of a free pericardial space

## Warnings

- Do not alter the introducer system in any way.
- Single-use disposable medical device. Do not resterilize and/or reuse this introducer system as adverse patient reactions may result since thorough cleaning of biological and foreign material is not possible.
- Ensure that the patient's hemodynamic parameters are acceptable prior to advancing the dilator or any other component. Continue hemodynamic monitoring throughout the procedure.
- Perform operations such as aspiration, component removal, and introducer exchanges slowly to minimize the potential for creating a vacuum in the introducer.
- Hypercoagulative conditions/anticoagulation should not be present or given until epicardial access has been obtained.
- Only those physicians who are specially trained in subxiphoid access should use this introducer system.
- During insertion, avoid creating excessive bends in the introducer or other components.
- Use fluoroscopy to verify the position of the introducer and other components and to assist guiding the devices through the patient anatomy.

## Precautions

- Inspect all components before use. Do not use if the package or items in the kit appear to be damaged or defective.
- Contents are sterile if package is unopened and undamaged.
- The French size specified on the dilator and obturator hubs indicates the outer diameter of these components. This should match the French size of the Agilis™ PF Introducer (as specified on the label). Do not attempt to insert into the introducer any device that has a distal tip or body size larger than the introducer size indicated.
- Ensure that the notch on needle stylet and the corresponding slot on the needle hub face upwards during insertion. This helps ensure that the needle tip is curved in the upwards direction during insertion. This in turn reduces the risk of accidental myocardial perforation/laceration during needle insertion.

- Do not attempt to use a guidewire larger than the maximum diameter specified on the package label.
- Prior to inserting the introducer into the patient, pre-assemble the deflectable introducer and dilator.
- The Agilis PF Introducer hemostasis valve cap is designed to interlock only with the supplied dilators and obturators. Misuse may result in complications.
- Do not remove dilator or introducer rapidly. Damage to the backbleed valve may occur.
- Do not deflect the introducer when the dilator has been inserted.
- If resistance is met when advancing or withdrawing the guidewire or introducer, determine the cause and correct the problem before continuing with this procedure.

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**Note**

Do not use the introducer as an abdominal cavity puncture tool.

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- Aspiration and fluid infusion (such as saline flush) should be carried out only through the sideport.
- This system should only be used with equipment that complies with international safety standards.
- Always straighten the introducer tip before inserting or removing this introducer from the patient. Prior to removing the introducer, verify that the tip is straight by viewing the tip on fluoroscopy.
- Dispose of this introducer system according to standard hospital procedures.
- Individual patient anatomy and physician technique may require procedural variations.
- Store in a cool, dry, dark place.

## Potential Complications

As with any catheterization procedure, potential complications include, but are not limited to:

- Thromboembolism
- Air embolism
- Local and systemic infection
- Bleeding or hematoma at puncture site
- Perforation (e.g., diaphragm, liver, lung and vessels)
- Thrombus formation
- Epicardial irritation
- Perforation of the heart chambers leading to cardiac tamponade
- Pericarditis
- Hemopericardium
- Esophageal injury
- Coronary artery injury
- Abdominal bleeding
- Pneumopericardium
- Atrial fibrillation (AF)
- Ventricular tachycardia (VT) requiring cardioversion
- Ventricular fibrillation (VF)
- Myocardial infarction

## How Supplied

The St. Jude Medical Agilis™ PF Introducer System is supplied sterile, for single use only, provided the package is unopened and undamaged.

## Recommended Patient Screening

Patients with the following pre-existing conditions may not be suitable for this procedure:

- Congenital absence of the pericardium
- Epicardial surface fat pad on the epicardium surface >5 mm
- Constrictive and adhesive pericarditis (large percentage of adhesion).
- Active infection

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**Note**

Ensure that the patient has been appropriately treated for infections and does not have any active infections, prior to undergoing this procedure.

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- Previous cardiac surgery
  - Myocardial infarction
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**Note**

These pre-existing conditions may inhibit access to areas of the epicardium due to pericardial fibrosis. Special care should be used when performing pericardial access procedures in these patients.

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- Hemodynamic instability
- Unstable angina

- Recent cerebral vascular accident (CVA)
- Presence of acute cardiac thrombus
- Acute conditions, such as electrolyte abnormality, acute ischemia, and drug toxicity.
- ~~Cardiac defibrillator epicardial patch.~~

### Procedural Considerations

The following are among the procedural considerations that should be examined prior to use of the introducer system. They are designed to better prepare the clinician for potential complications associated with the subxiphoid technique and pericardial anatomy in general, such as air emboli.

- Prior to catheterization, the patient's clotting system should be evaluated. Use anticoagulant as training and experience may dictate.
- Subxiphoid procedures should be performed only in facilities appropriately equipped and staffed to perform such procedures. Laboratory capabilities should include, but are not limited to:
  - Intracardiac pressure monitoring
  - Systemic pressure monitoring
  - Pericardiocentesis
  - Surgical backup
  - Appropriate monitoring of vital signs throughout the procedure
  - Familiarity with contrast media injection and management of untoward reactions to contrast media

### Note

Excessive contrast may reduce visibility under fluoroscopy.

## Pericardial Access

Use the Agilis™ PF Introducer system to gain access to the pericardial space with a subxiphoid procedure. This serves as a conduit during delivery of St. Jude Medical devices.

Use fluoroscopic guidance to gain access to the pericardial space.

1. Create a subxiphoid incision that sufficiently allows introducer access and maneuverability.
2. Use the Tuohy needle to gain access to the pericardial space. Pass the needle above the level of the diaphragm rather than traversing through the diaphragm so that the intra-abdominal viscera and subdiaphragmatic blood vessels may be avoided. Use a left lateral fluoroscopic view to identify the precise location of the diaphragm.
3. To confirm entry into the pericardial space, inject small amounts of contrast.
4. Insert the guidewire into the Tuohy needle.
5. Advance the guidewire into the pericardial space. Passage of the guidewire into the pericardial space is best confirmed using a Fluoroscopic Left-Anterior-Oblique (LAO) projection.
6. Remove the Tuohy needle while retaining the guidewire in place.
7. Flush the introducer and the dilator with sterile saline.
8. If the introducer tip is already deflected, use the deflection control mechanism to straighten the tip. This mechanism is located on the introducer handle.
9. Insert the dilator into the introducer and lock the dilator into the hemostasis cap.
10. Place the dilator over the guidewire. Advance the introducer and dilator into the pericardial space.
11. Remove the dilator and guidewire from the introducer.
12. Insert the obturator into the introducer and lock the obturator into the hemostasis cap.
13. With the obturator in place, maneuver the introducer and deflect the introducer tip to access the desired location.
14. Remove the obturator and if required, carefully adjust the introducer position for subsequent cardiac diagnostic and/or therapeutic device delivery.
15. Always straighten the introducer tip before removing the introducer from the patient. When the device is inside the patient, verify the tip position using fluoroscopy prior to removing the introducer system.

### Note














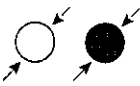
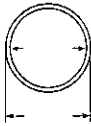
If required, remove air by closing the hemostasis valve and withdrawing air through the three-way stopcock.

## Available Accessories

Additional accessories available for use with the St. Jude Medical Agilis™ PF Introducer System include:

- Agilis™ PF Introducer Accessory Kit (0.032", 100cm guidewire, 13Fr. Dilator, 13Fr. Obturator and 17Ga. Tuohy Needle)

# Symbols

	Store in a cool, dark, dry place
	Sterilized using ethylene oxide
	Do not reuse
	Consult instructions for use
	Use by
	Do not use if package is damaged
	Manufacturer
	Manufacturing date
	<p>Aligned to this device in accordance with European Council Directive 93/42/EEC and 1993/42/EEC.</p> <p>Manufacturer's declaration that this device is in compliance with the essential requirements and other relevant provisions of these Directives.</p>
	Lot number
	Authorized representative in the European Community
	Temperature limitations
	Prescription only
	Inner diameter
	Outer diameter
	Inner and outer diameters



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -W066-G609  
Silver Spring, MD 20993-0002

St. Jude Medical, CRM  
c/o Ms. Geena George  
Associate Regulatory Submission Specialist  
15900 Valley View Court  
Sylmar, CA 91342

SEP 29 2011

Re: K111943  
Trade/Device Name: Agilis™ PF Introducer System  
Regulatory Number: 21 CFR 870.1340  
Regulation Name: Catheter introducer  
Regulatory Class: II (two)  
Product Code: 74 DYC  
Dated: September 19, 2011  
Received: September 20, 2011

Dear Ms. George:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to


<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

for

  
Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



## Indications for Use

510(k) Number (if known):   K111943  

Device Name: St Jude Medical Agilis™ PF Introducer System and accessories

**Indications for Use:** The Agilis™ PF Introducer System is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate electrophysiology studies

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number   K111943